VIOLATIVE SALES OF PRESCRIPTION DRUGS

5081. (F. D. C. No. 36614. S. Nos. 33-514 L, 58-082 L, 58-808/9 L.)

INFORMATION FILED: 1-19-55, N. Dist. Ill., against **2600 State Drugs, Inc., Chicago, Ill., Edward Kravetz (vice president and manager of the drug department), Melburn Holtzman (secretary-treasurer and apprentice pharmacist), and Raymond Holtzman (clerk).**

CHARGE: Between 1-16-54 and 2-24-54, *amphetamine sulfate tablets* (counts 1, 2, and 3) were dispensed three times and *Sulfisoxazole tablets* (count 4) were dispensed once without a prescription.

DISPOSITION: On 3-14-55, the defendants filed a motion for dismissal of the information on the ground that the provisions of the Act which the defendants were charged to have violated were unconstitutional. This motion was denied by the court on 5-10-55. On 6-6-55, pleas of not guilty were entered by the corporation to all 4 counts of the information; by Edward Kravetz to counts 1 and 2; by Raymond Holtzman to count 3; and by Melburn Holtzman to count 4.

The case came on for trial before the court without a jury on 9-21-55 and was concluded on 10-3-55, with a verdict of guilty and the imposition of the following sentences by the court: $1,000 fine, plus costs, against the corporation; $500 fine and imprisonment of 3 months against Edward Kravetz; and $250 fine and imprisonment of 3 months against Raymond Holtzman and Melburn Holtzman.

On 10-13-55, a notice of appeal to the United States Court of Appeals for the Seventh Circuit was filed, and on 7-11-56, this court handed down the following opinion:

SWAIM, *Circuit Judge:* "The defendant, 2600 State Drugs, Inc., and the individual defendants, Edward Kravetz, Melburn Holtzman and Raymond Holtzman, all of whom were either officers or employees of the defendant drug corporation, were charged in a criminal information with having sold, without a prescription, certain drugs in violation of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. Section 301, *et seq.* In a trial before the District Court all of the defendants were found guilty of violating the Act.

"The principal question presented by this appeal is whether or not those sections of the Federal Food and Drug Act which prohibit the sale of dangerous drugs without a prescription are sufficiently definite to give reasonable notice to persons bounded by the proscriptions of the Act and subject to its penalties.

"The applicable parts of Section 331 of 21 U. S. C. A. provide:

> Prohibited acts—
> The following acts and the causing thereof are hereby prohibited:
> * * * * * * *
> (b) The adulteration or misbranding of any * * * drug * * * in interstate commerce.
> * * * * * * *
> (k) The adulteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or *the doing of any other act* with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded. [Our emphasis.]

Section 353 of 21 U. S. C. A., concerning prescriptions by physicians, prescription requirements and the misbranding of drugs, provides:

(b) (1) A drug intended for use by man which—

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(B) Because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(C) is limited by an effective application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug * * *. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

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(4) A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law prohibits dispensing without prescription." * * *

Section 355 of 21 U. S. C. A., concerning new drugs and the necessity of effective application, provides:

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug.

(b) Any person may file with the Secretary [of Health, Education and Welfare] an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; * * * and (6) specimens of the labeling proposed to be used for such drug.

"At the beginning of the trial of this case the parties stipulated that the drugs which the defendants were accused of dispensing without a prescription were drugs within the meaning of 21 U. S. C. A. Section 353 (b) (1) (B), as amended, and which prior to January 16, 1954, were shipped in interstate commerce into the State of Illinois and were held in the manufacturer's original labeled bottle, the label upon which included the statement, 'Caution: Federal Law Prohibits Dispensing Without Prescription.'

"In this case the evidence in the record furnished a sufficient basis for the finding of the trial court that the drugs in question could be safely used only under the direction and supervision of a physician and that the defendants dispensed said drugs without prescriptions, as charged in the information.

"Although admitting that the drugs here in question had been shipped in interstate commerce, that the container carried a label stating that federal law prohibited the sale of the drugs without a prescription, and that there was sufficient evidence to support the trial court's findings that the defendants had made sales of such drugs without prescriptions, the defendants insist that the language of the statute is so vague, uncertain and indefinite as to fall short of the constitutional requirements of due process of law. On this point the defendants contend that the statute here in question is so vague and indefinite 'that men of common intelligence must necessarily guess at its meaning and differ as to its application,' and that, therefore, the statute is too vague, indefinite and ambiguous to constitute a legal basis for a criminal charge. We think the provisions of this Act are sufficiently definite to support a criminal charge for the violation of the Act.

"In *Boyce Motor Lines* v. *United States*, 342 U. S. 337, the Court was considering the validity of a regulation promulgated by the Interstate Commerce Commission which provided that drivers of motor vehicles transporting certain explosives and poisonous gases should 'avoid, so far as practicable, and where feasible, by prearrangement of routes, driving into or through congested thoroughfares, places where crowds are assembled, street car tracks, tunnels, viaducts, and dangerous crossings.' In its opinion in that case the Court said (page 340):

> A criminal statute must be sufficiently definite to give notice of the required conduct to one who would avoid its penalties, and to guide the judge in its application and the lawyer in defending one charged with its violation. But few words possess the precision of mathematical symbols, most statutes must deal with untold and unforeseen variations in factual situations, and the practical necessities of discharging the business of government inevitably limit the specificity with which legislators can spell out prohibitions. Consequently, no more than a reasonable degree of certainty can be demanded. Nor is it unfair to require that one who deliberately goes perilously close to an area of proscribed conduct shall take the risk that he may cross the line.

"In *Sproles* v. *Binford*, 286 U. S. 374, the Court was considering a Texas statute which prohibited the carriage of overweight and oversize loads by commercial carriers but which permitted the granting by the State Highway Department of permits, for ninety days, for the carrying of such loads 'as cannot be reasonably dismantled.' The statute provided further that these loads were to be carried 'by the shortest practicable route.' The Court there held (page 393) that the phrase, 'shortest practicable route,' was not an expression too vague to be understood. The Court explained:

> The requirement of reasonable certainty does not preclude the use of ordinary terms to express ideas which find adequate interpretation in common usage and understanding. [Citing authorities.] The use of common experience as a glossary is necessary to meet the practical demands of legislation. In this instance, to insist upon carriage by the shortest *possible* route, without taking the practicability of the route into consideration, would be but an arbitrary requirement, and the expression of that which otherwise would necessarily be implied, in order to make the provision workable, does not destroy it. 286 U. S. at page 393.

"Another factor which we must consider in the instant case is the fact that the provisions of the sections of the Act here under consideration were to bind *pharmacists* and to subject them to penalties in case of violations.

"To ship these drugs in interstate commerce it was necessary for the manufacturer to qualify them pursuant to the requirements of Section 355 of the Act. The drugs were qualified for interstate shipment on the condition that the container in which they were shipped bear a label which read, 'Caution: Federal law prohibits dispensing without prescription.' Section 331 (k) of the Act prohibited the removal of this label. The evidence here showed that when the sales of these drugs were made the label on the container was intact. It would seem clear that any pharmacist who sold these drugs without a prescription would necessarily know that he was violating the Food and Drug Act but that in order to make such sales the defendants were willing to defy the prohibitions of the Act.

"The defendants also insist that that part of Section 353 (b) (1) (C) of the Act which provides that 'The act of dispensing a drug contrary to the provisions of this paragraph [without the prescription of a physician] shall be deemed to be an act which results in the drug being misbranded while held for sale,' goes beyond the purpose of the Food and Drug Act, the sole purpose of which is to inform and so protect the ultimate consumer that he may be guarded against misrepresentation. The defendants say that the arbitrary extension of the meaning of the word 'misbranded' constitutes an unreasonable exercise of the commerce powers of Congress and violates the Fifth and Tenth Amendments of the Constitution of the United States. This contention we think is answered in *United States* v. *Carlisle* (No. 15898), 5 Cir., ——F. 2d——, which was decided May 31, 1956. The court in the *Carlisle* case pointed out that the Act sets out the only way the drugs there in question could be dispensed and then goes on to say that the act of dispensing the drugs contrary to the provisions of the Act shall be deemed to be an act which results in the drug being misbranded. The court there said (page 6 of the slip opinion):

> This established, by law in this section, there is required only resort to 21 U. S. C. 331 (k), which denounces the offense of misbranding, and to Sec. 333, which fixes the penalty for that offense.

The court concluded:

> * * * that the sections taken together have provided as clearly as though it had all been written out in the same section, that one dispensing drugs of the kind dealt with here, contrary to the provisions of Sec. 353 (b) (1) shall be guilty of, and subject to the punishment provided by law for, an act of misbranding.

The court there held (page 7 of the slip opinion):

> * * * that the use of the word "deemed" in the Act creates an irrebuttable presumption, a rule of substantive law, and that the doing of the prohibited act, dispensing the drugs * * * without the authorization of the prescriber, makes refilling misbranding and subjects the dispenser to the penalties provided for misbranding.

"The defendants also insist that the sales of these drugs without prescriptions constituted purely intrastate transactions, that these drugs did not remain a part of the stream of interstate commerce, and that the sales of the drugs at retail did not affect interstate commerce directly or indirectly. In support of this contention the defendants cite *Schechter Corp* v. *United States*, 295 U. S. 495, 544. But we think this contention is answered in *United States* v. *Sullivan*, 332 U. S. 689. In the latter case the defendant Sullivan, a retail druggist in Columbus, Georgia, purchased from a wholesale druggist in Atlanta, Georgia, a bottle of sulfathiazole tablets which had been shipped in interstate commerce from Chicago, Illinois. The label on the bottle which the defendant received gave adequate directions for the use of the tablets and adequate warning to protect the ultimate consumer from dangers incident to their use. The defendant removed some of the tablets from the original labeled bottle and placed them in a pill box labeled with the name of the drug but without adequate directions for use or warnings of danger. The Court there, after pointing out that the defendant had bought the drugs over six months after the interstate commerce shipment to the purchaser in Atlanta had been completed, said (pages 696 and 697):

> But the language used by Congress broadly and unqualifiedly prohibits misbranding articles held for sale after shipment in interstate commerce, without regard to how long after the shipment the misbranding occurred, how many intrastate sales had intervened, or who had received the articles at the end of the interstate shipment. Accordingly we find that the conduct of the respondent falls within the literal language of section 301 (k) [section 331 (k) of the present Act].
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> * * * The words of paragraph (k) "while such article held for sale after shipment in interstate commerce" apparently were designed to fill this gap [left by paragraphs (a), (b) and (c)] and to extend the Act's coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer.

In the *Sullivan* case the Court rejected the contention that its holding permitted Congress to invade the powers reserved by the Constitution to the states, pointing out that it had held in *McDermott* v. *Wisconsin*, 228 U. S. 115, that the authority of Congress to make such requirements was a proper exercise of its powers under the commerce clause.

"We think that the principles announced by the Court in the *Sullivan* and *McDermott* cases require us to hold here that Congress properly exercised its powers under the commerce clause by providing that drugs which have been transported in interstate commerce and which are dangerous to human beings unless their use is prescribed by a physician should not be dispensed except on the prescription of a physician.

"The judgment of the District Court is AFFIRMED."

A petition for a writ of certiorari was filed with the United States Supreme Court. On 10-8-56, the Supreme Court denied the petition.